



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

000826 HZ12/0621
ALSTON & BIRD LLP
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CHARLOTTE NC 28280-4000

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/446,402	12/20/99	004	MCGARRY, S	1635 06/21/01
First Named Applicant	BLACK JR.,			

TITLE OF INVENTION
COMPOSITIONS AND METHODS FOR ACTIVATING GENES OF
INTEREST

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEES DUE	DATE DUE
1 5722-2	435-069.100	112	UTILITY	YES	\$620.00	09/21/01

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.
PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS
APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.
Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

Notice of Allowability	Application No.	Applicant(s)
	09/446,402	BLACK JR., CHARLES ALLEN
	Examiner	Art Unit
	Sean McGarry	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to 4/9/01.
2. The allowed claim(s) is/are 2-4 and 16.
3. The drawings filed on _____ are acceptable as formal drawings.
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some*
 - c) None
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE FOR SUBMITTING NEW FORMAL DRAWINGS , OR A SUBSTITUTE OATH OR DECLARATION. This three-month period for complying with the REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL is extendable under 37 CFR 1.136(a).**

6. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7. Applicant MUST submit NEW FORMAL DRAWINGS
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review(PTO-948) attached
 - 1) hereto or 2) to Paper No. _____.
 - (b) including changes required by the proposed drawing correction filed _____, which has been approved by the examiner.
 - (c) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

8. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE / SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

- | | |
|--|--|
| <input type="checkbox"/> Notice of References Cited (PTO-892) | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>2,5</u> . | <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | <input type="checkbox"/> Other |
- WILLIAM N. PHILLIPS
PATENT ANALYST*

file #10-B
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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Eric Kron and Murray Spruill on 6/19/01.

A communication was mailed to applicant on 6/19/01 that indicated that the response filed 4/9/01 was incomplete. The paper copy of the sequence listing has been located and entered into the application file. The requirements of the communication mailed 6/19/01 are hereby withdrawn.

During the interview the examiner indicated that a restriction requirement would be made in the instant application and the restriction requirement is set forth below.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, drawn to a masked expression cassette.



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Group II, claim(s) 10-15, drawn to methods of controlling the expression of a protein of interest.

3. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The methods of group II can be performed using other than the masked expression cassette of Group I.

4. During a telephone conversation with Eric Kron on 6/19/01 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-4. It was indicated by applicant representative that these claims would be pursued in a divisional application..

5. The application has been amended as follows:

Nonelected claims 5-15 have been canceled.

Claim 1 has been canceled and rewritten as new claim 16.

Claim 16. A masked expression cassette comprising a first strand comprising an RNA sequence which encodes a protein of interest wherein the RNA sequence is linked downstream of a flanking sequence, and a translation initiation site operably linked upstream of the RNA sequence; and, a second strand bound to the flanking sequence, wherein the second strand

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comprises an antisense sequence corresponding to the flanking sequence and a target nucleic acid sequence, where when the masked expression cassette is contacted with the target nucleic acid the second strand dissociates from the cassette allowing expression of the protein of interest.

In claim 2, line 1, "1" has been deleted and replaced with --16--.

In claim 3, line 1, "1" has been deleted and replaced with --16--.

In claim 3, line 1, "comprises" has been deleted and replaced with --is--.

In claim 4, line 1, "1" has been deleted and replaced with --16--.

6. The following is an examiner's statement of reasons for allowance: The composition claims related to the amended claims above were rejected under 35 U.S.C. 112, first paragraph. This rejection of the compositions was based on the utility asserted in the specification drawn to *in vivo* use. The specification however does include *in vitro* utilities (see page 3 and Figure 7, for example).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean McGarry whose telephone number is (703) 305-7028.

SRM

June 20, 2001



SEAN McGARRY
PRIMARY EXAMINER

